DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2008

Guidant Cardiac Surgery
c/o Mr. Eric Henning
Project Leader
KEMA Quality B.V.
4377 County Line Road
Chalfont, PA 18914

Re: Re: K041340
Trade/Device Name: The Guidant Microwave Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II (two)
Product Code: OCL, NEY
Dated: July 9, 2004
Received: July 13, 2004

Dear Mr. Henning:

This letter corrects our substantially equivalent letter of July 28, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

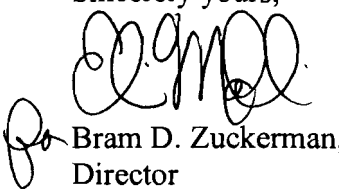
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K041340

Device Name: The Guidant Microwave Ablation System

Indications for Use

The Guidant Microwave Ablation System is indicated for the surgical ablation of soft tissue, and striated, cardiac, and smooth muscles. The System is a device indicated for use, under direct visualization, in surgical procedures, including minimally invasive cardiac surgery procedures. The probes ablate the target tissue by creating an inflammatory response, or thermal necrosis.

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number [redacted]

SECTION 2 – 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

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Guidant Corporation
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Device Name
Trade Name: Guidant Microwave Ablation System
Common Name: Microwave Ablation System
Classification Name: Cryosurgical unit and accessories (21 CFR 878.4350);

Identification of Predicate Devices

AFx Microwave Ablation System and Accessories	K003978
FLEX 10 Accessory for the AFx Microwave Ablation System	K013946
CryoGen Cardiac Cryosurgery System	K974320
Heartport™ Maze System: Cryoprobe Set	K970496

Indications for Use
The Guidant Microwave Ablation System is indicated for the surgical ablation of soft tissue, and striated, cardiac, and smooth muscles. The System is a device indicated for use, under direct visualization, in surgical procedures, including minimally invasive cardiac surgery procedures. The probes ablate the target tissue by creating an inflammatory response, or thermal necrosis.

Device Description
The Guidant Microwave Ablation System consists of a microwave generator and hand-held ablation probe accessories. The probe is available in two versions: the FLEX 4 and the FLEX 10. The ablation probe contains the microwave antenna that emits the microwave energy.

The microwave generator's output (2450 MHz) is conducted through the output cable, into the cabling of the Probe, and out the antenna at the distal section of the Probe. Energy is expressed in a pattern that is radial to the orientation of the ablating tip. Shielding in the ablating tip inhibits microwave energy expression into non-targeted tissue. The target tissue contains polar molecules (most notably water), which vibrate in response to the induced electromagnetic microwave field. This vibration creates heat through friction, raising the temperature of the tissue throughout the area being ablated. Upon reaching a certain temperature, the tissue becomes necrotic, and thus fully ablated.

FLEX 4 has a flexible antenna fixed at the distal end of the probe. FLEX 10 has a flexible antenna that can be moved along the distal end of the probe.

Testing in Support of Substantial Equivalence Determination

There are no changes in the product's design, technology, materials, manufacturing, performance, specifications, and method of use or the instructions for use (except for the updated product name and indication statement).

The proposed change is a labeling change to make the product's indication statement more precise and consistent with those of the predicate devices with respect to the surgical access to the tissue. This change has no impact on the target population for the device.

In view of the above, the testing conducted and included previously in the 510(K) submissions K003978 and K013946 remains valid and sufficient, in the opinion of the sponsor, and consequently no additional testing was necessary for the substantial equivalence determination.

Substantial Equivalence Conclusion

The subject Guidant Microwave Ablation System has been on the market as the AFx Microwave Ablation System (K003978 and K013946).

There are no changes in the product's design, technology, materials, manufacturing, performance, specifications, and method of use or instructions for use (except for the updated product name and indication statement).

The primary change is a labeling change to make the product's indication statement more precise and consistent with those of the predicate devices with respect to the surgical access to the target tissue. This change has no impact on the target population for the device.

The Guidant Microwave Ablation System and the predicates are widely used by cardiothoracic surgeons via a variety of surgical approaches, including minimally invasive approaches, to access and ablate the target tissue. For all these devices, the method of use is similar in that the surgeon uses a clinically appropriate surgical access to reach the target tissue and to lightly position the device on it. The physical characteristics of the subject device with respect to the surgical access and the use are similar to those of the predicates and do not create any new issues of safety and efficacy.

In view of the above, the subject device is judged substantially equivalent to the predicate devices.